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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09,413,109	10-06-1999	WEI-WEI ZHANG	INRP,087,515	1595

7590

04/01/2003

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EXAMINER

GUZO, DAVID

ART UNIT

PAPER NUMBER

1636

DATE MAILED: 04/01/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/413,109

Applicant(s)

ZHANG ET AL.

Examiner

David Guzo

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-97 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 22-31, 36, 37, 39-48, 53, 54, 56-68, 73, 74, 76-86, 91, 92 and 94-97 is/are rejected.
- 7) ☒ Claim(s) 32-35, 38, 49-52, 55, 69-72, 75, 87-90 and 93 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 October 1999 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

Detailed Action

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 79, 95, 96 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-26 and 70-72 of U.S. Patent No. 6,143,290 (hereafter the '290 patent). Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic to all that is recited in claims 24-26 and 70-72 of the '290 patent. That is, claims 24-26 and 70-72 of the '290 patent fall entirely within the scope of the instant claims 79, 95-96 or, in other words, claims 79, 95-96 are anticipated by claims 24-26 and 70-72 of the '290 patent. Specifically, the method of inducing cell death in tumor cells in a patient comprising directly injecting the tumor with a recombinant adenovirus which does not express functional E1b and contains a sequence encoding a wild-type p53 protein operably linked to the CMV IE promoter recited in the '290 patent is encompassed within the instantly claimed method of treating a human cancer patient, said method comprising administering by direct injection into the tumor of any

adenoviral composition comprising an adenoviral vector comprising a sequence encoding a wild-type p53 protein, said sequence being under control of a CMV IE promoter. With regard to claim 96, it is noted that expression of wild-type p53 kills tumor cells having p53 null or mutated non-functional p53 proteins by apoptosis.

Claims 22-31, 36-37, 39-48, 53-54, 56-68, 73-74, 76-86, 91-92, 94-97 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 9-13 and 24-63, 65-66, 68-69, 71-74 of copending Application No. 08/459,713. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications recite the same methods for treatment of human cancer patients with recombinant adenoviral vectors. The instant claims are generic to all that is recited in claims 9-13 and 24-63, 65-66, 68-69 and 71-74 of the '713 application. That is, the instant claims fall entirely within the scope of the claims of the '713 application, in other words, the instant claims are anticipated by the claims of the '713 application. Specifically, the methods of treating specific human cancers recited in the '713 application are encompassed within the instant method of treating any human malignancy. The specific adenoviral vector constructs recited in the methods of the '713 application are encompassed within the instant claims reciting use of any adenoviral vectors. Additionally, both applications recite the same methods of administering adenoviral vectors to patients at the same concentration ranges of adenoviral vectors and both recite adenoviral vectors with the p53 gene operably linked to the CMV IE promoter.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

No Claims are allowed.

Claims 32-35, 38, 49-52, 69-72, 75, 87-90 and 93 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242. Faxes may be submitted directly to the examiner at (703) 746-5061.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

David Guzo
March 29, 2003

DAVID GUZO
PRIMARY EXAMINER
